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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,596	09/29/2005	Kam Man Hui	P08512US00/BAS	9105

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EXAMINER	
HOFFMAN, SUSAN COE	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,596	HUI, KAM MAN	
	Examiner	Art Unit	
	Susan Coe Hoffman	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 13 December 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed December 13, 2004 has been received and entered.

2. Claims 1-14 are currently pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 7-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are directed to "use" claims which are a non-statutory category of invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5, 7-11 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the risk of cancer or inflammation, does not reasonably provide enablement for prevention of cancer or inflammation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of

working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's claims are broadly drawn to a composition that is able to prevent cancer and disease associated with inflammation. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition in each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent cancer or inflammation for all potential causes of cancer or inflammation. In addition, the art teaches that cancer prevention requires a variety of diet and lifestyle changes that are not discussed by applicant. Furthermore, the art acknowledges that these steps only reduce the risk of acquiring cancer and do not assure complete prevention (see www.cnn.com/HEALTH/library/CA/00024.html). In regards to inflammatory diseases, the art acknowledges that an inflammatory disease, rheumatory arthritis, is currently not able to be prevented because the causes of the disease are not fully understood (see www.webmd.com/hw/rheumatoid_arthritis/aa19581.asp). Thus, since applicant's specification does not show prevention of cancer and inflammatory diseases and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually function as claimed. Therefore, the claims are not considered enabled for the prevention of cancer and inflammatory diseases.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 6, 12, and 14 are indefinite because it is unclear what diseases are encompassed by a "disease associated with inflammation." Applicant has not defined which diseases are considered to be encompassed by this term; thus, the metes and bounds of the claim are unclear.

6. Claims 7-12 provide for the use of a *Fagopyrum dibotrys* extract, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 7-12 are also rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Furthermore, as discussed above, "use" type claims are a non-statutory category of invention. Thus, it is unclear if applicant is intending these claims to be method or composition claims. For the sake of examination, these claims will be examined a composition claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, and 4-14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. Pub. No. 2001/0018076.

US '076 teaches a pharmaceutical composition extracted from *Fagopyrum cymosum*. According to applicant's specification, *F. cymosum* is a synonym for *F. dibotrys* (see page 1). The extract is made by extracting crushed *F. cymosum* rhizome with methanol or ethanol, with ethanol being preferred. The solvent is evaporated from the liquid extract under reduced pressure to create a concentrated extract. The extract is then fractionated by macroporous resin (see paragraphs 34, 38, and Example 1 on pages 7 and 8). The extract is made into a pharmaceutical composition which is used to treat cancer and inflammation. Lung cancer is specifically taught (see paragraphs 96 and 97).

The reference does not specifically teach that the composition is able to treat breast cancer, liver cancer and melanoma. However, as discussed above in paragraph 6, claims 8, 10, and 11 are being examined as method claims. Thus, since the reference teaches the same composition as claimed, the reference composition would inherently have the same properties as the claimed composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. Pub. No. 2001/0018076.

As discussed above, US '076 teaches the same method of making the pharmaceutical extract composition as claimed. The reference specifically teaches drying the extract under reduced pressure and teaches using excipients (see paragraph 59) but does not specifically teach using an exicipient during the drying step. However, it would have been a routine matter of general experimentation to determine the best point at which to add the exicipient to the pharmaceutical extract. Thus, the addition of the exicipient during the drying step is considered to be an obvious modification of the method of extraction taught by the reference.

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe Hoffman whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday-Thursday, 9:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SHoffman
11-2-06

Susan Coe Hoffman
Primary Examiner
Art Unit 1655